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| APPLICATION NO | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|----------------|-------------|----------------------|---------------------|------------------|
| 09-779,334 | 02 08 2001 | Carsten Sjoholm | NOVT 100 | 9041 |

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PATREA L. PABST
HOLLAND & KNIGHT LLP
SUITE 2000, ONE ATLANTIC CENTER
1201 WEST PEACHTREE STREET, N.E.
ATLANTA, GA 30309-3400

[REDACTED] EXAMINER

WEBER, JON P

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1651

DATE MAILED: 08/06/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|---------------------------------|------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/779,334 | SJOEHOLM ET AL. |
| | Examiner Jon P. Weber, Ph.D. | Art Unit 1651 |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 23 May 2002.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-10 and 13 is/are pending in the application.
- 4a) Of the above claim(s) 1-5,8-10 and 13 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 6 and 7 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. _____.
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application)

Attachment(s)

- 1) Notice of References Cited (PTO-892)
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) Information Disclosure Statement (PTO-1449)
4) Interview Summary (PTO-414a, Paperless)
5) Notice of Informal Patent Application (PTO-152)

- 6) Other _____

Status of the Claims

The response with amendments filed 23 May 2002 has been received and entered. Claims 1-10 and 13 have been presented for examination.

Election/Restrictions

The amendment of 23 May 2002 significantly changed the claims under consideration. Accordingly they are regrouped as follows:

- I. Animal feed comprising protease and method of making - Claims 1-5 and 9-10.
- II. Feed Additive comprising protease - Claims 6-7.
- III. Feed Additive comprising protease and glycanase - Claims 8 and 13.

Applicant's election with traverse of original Group II, feed additive and method of making, now Group II, claims 6-7 in Paper No. 13, filed 23 May 2002 is acknowledged. The traversal is on the ground(s) that 1) it is impossible to search a different group when the claims are dependent, 2) features in the different groups are the same, hence, no burden of search.

This is not found persuasive because Group I is an animal feed, a material containing protein and carbohydrate, to which proteases have been added. The addition of the proteases necessarily modifies the protein content of the feed to at least partially hydrolyze the feed to produce peptides and amino acids. The resulting feed mixture is substantially different from the starting materials and substantially different from the additive of Group II. All three of the groups may use a protease **selected from** two different kinds of proteases, subtilisin and a

substantially different composition from the proteases having a molecular weight of 100,000.

activities can act upon a substrate comprising both protein and carbohydrate and change both whereas the additive having only protease cannot act upon carbohydrate content. The protease subcombination of Group II clearly has separate utility, for example, in inactivating viruses, depilating and bathing hides, or peptide synthesis to name a few. The combination of Group III can be used for degrading municipal or medical waste containing both protein and carbohydrate content. Finally, it is remarked that restriction is made between inventions, not between claims. The claims are assigned to their respective inventions even if a claim is listed more than once.

The requirement is still deemed proper and is therefore made FINAL. Claims 1-5, 8-10 and 13 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 13.

Specification

The disclosure is objected to because it contains an embedded hyperlink and/or other form of browser-executable code at pages 3, 13 and 39 (the disclosure should be checked carefully for others). Applicant is required to delete the embedded hyperlink and/or other form of browser-executable code. See MPEP § 608.01.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification is objected to and claims 6-7 rejected under 35 U.S.C. § 112, first paragraph, as failing to provide an adequate written description of the invention, failing to provide an enabling disclosure and failing to present the best mode contemplated by applicant for carrying out the invention without complete evidence either that the claimed biological materials (the microorganisms that are sources of the claimed acid stable subtilisins) are known and readily available to the public or complete evidence of the deposit of the biological material.

Since a deposit **has** been made under the terms of the Budapest Treaty (page 37 of the disclosure), then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney or record over his/her signature, and registration number, stating that the specific strain has been deposited under the Budapest Treaty **and** that **all** restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

Claim Objections

Claim 6 is objected to because of the following informalities: The term SSI is used without explanation. Uncommon abbreviations should be spelled out at the first instance. Appropriate correction is required.

Claim Rejections - 35 USC § 102 and 103

A person shall be entitled to a patent unless

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 6-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Heynigen et al. (1971), Van Heynigen (1972) or Outrup et al. (US 5,597,720).

Van Heynigen et al. (1971) and Van Heynigen (1972) both disclose the alkaline protease from *Acremonium kiliense* (ATCC 20338) in solutions containing various trace and macro minerals as defined in the instant disclosure. This is one of the preferred acid-stable subtilisin proteases identified at page 5 of the disclosure.

Outrup et al. (US 5,597,720) discloses the alkaline protease from *Bacillus* sp. PD498, NCIMB 40484 in solutions containing trace and macro minerals as defined in the instant disclosure. This is one of the preferred acid-stable subtilisin proteases identified at page 5 of the disclosure.

Claims 6-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Aunstrup et al. (US 3,674,643).

Aunstrup et al. (US 3,674,643) discloses the alkaline protease from *Bacillus alkalophilus* NCIB 10436 in solutions containing trace and macro minerals as defined in the instant instantly disclosed of NCIB 10438. Given that the comparable properties of the alkaline protease

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from the 10436 strain are the same as those of the alkaline protease from the disclosed 10438 strain, the alkaline protease either inherently is an acid-stable subtilisin protease or would be reasonably expected to be an acid-stable proteinase.

Claims 6-7 are rejected under 35 U.S.C. 102(b) as anticipated by Ichishima et al. (US 4,480,037).

Ichishima et al. (US 4,480,037) discloses that alkaline protease from *Bacillus alcalophilus* NCIB 10438 is known in the art (column 9) and demonstrates some of its physical and chemical properties (Table 2). The assay solution used to determine the kinetic properties contains trace and macro minerals (see column 6 for assay conditions). This is one of the preferred acid-stable subtilisin proteases identified at page 5 of the disclosure.

Claims 6-7 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Horikoshi et al. (US 4,052,262).

Horikoshi et al. (US 4,052,262) discloses the alkaline subtilisin protease from *Bacillus* genus in solutions containing trace and macro minerals as defined in the instant disclosure. As can be seen from Figure 5, the protease is about 80% active at pH 4 indicating that it is acid stable.

The amount referenced in claim 7 is not given patentable weight in the above rejections inasmuch as it does not materially change the composition itself, i.e., it is a quantity which is an extrinsic rather than an intrinsic property.

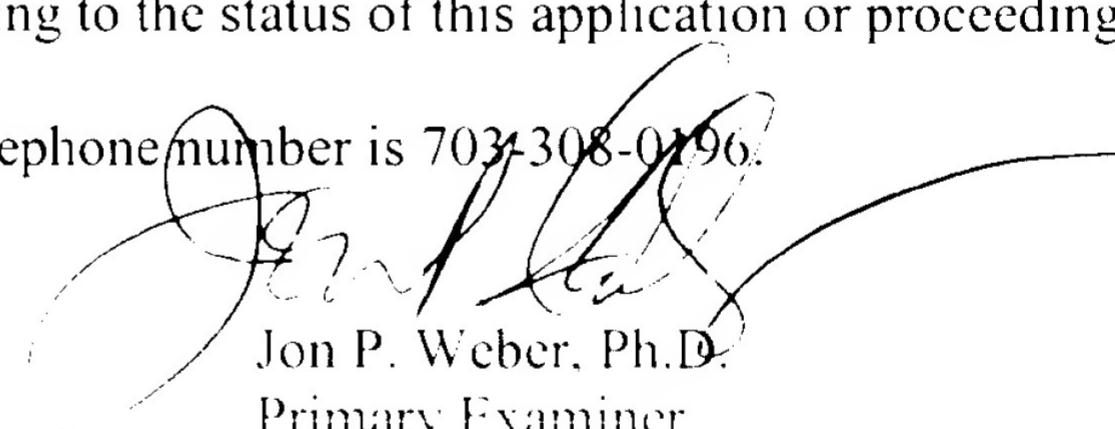
4,062,732) and Schindler et al. (US 4,473,644) each disclose acid-stable proteases for which it cannot be determined from the disclosure if the proteases are subtilisins as defined in the instant disclosure.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jon P. Weber, Ph.D. whose telephone number is 703-308-4015. The examiner can normally be reached on daily, off 1st Fri, 9/5/4.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 703-308-4743. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



Jon P. Weber, Ph.D.
Primary Examiner
Art Unit 1651

JPW
August 1, 2002